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EXAMINER	
PEPITONE, MICHAEL F	
ART UNIT	PAPER NUMBER
1796	

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08/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,746	BABA ET AL.	
	Examiner	Art Unit	
	MICHAEL PEPITONE	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,6 and 8-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,6 and 8-37* is/are rejected.

7)☒ Claim(s) *11 and 12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 11-12 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 11 recites a water content of 10 to 60 wt%, which fails to further limit the water content of claim 1; claim 12 recites a water content of 32 to 55 wt%, which is the same water content of claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4, 6, and 8-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwata *et al.* (US 2002/0016383) in view of Shibata *et al.* (US 4,547,543), when taken with Katagiri *et al.* (JP 06-214197) {English machine translation of Katagiri *et al.* (JP 06-214197) was used}.

Regarding claims 1-2, 4, 6, 8, 11-14, and 17-18: Iwata *et al.* disclose long wearable soft contact lenses [instant claim 18] (¶ 1-2), wherein a specific embodiment {ex. 14} comprises 60 parts by weight {pbw} of polysiloxane dimethacrylate having polyoxoethylene groups and urethane groups {C3 (¶ 276-277)}; 35 pbw N-vinylpyrrolidone {NVP}; 5 pbw cyclohexyl methacrylate {CH}; 1 pbw ethyleneglycol dimethacrylate {ED} (¶ 170), and 0.5 pbw 2,4,6-trimethylbenzoyldiphenylphosphinoxide {TPO} (¶ 294). The resulting lens has a water content of 38% and an oxygen permeability {Dk} (¶ 256-257) of 81 (x 10^{-11} cm^2/sec) (¶ 312; Table 3, ex. 14). Iwata *et al.* disclose ex. 35 comprising 50 parts by weight {pbw} of polysiloxane dimethacrylate having polyoxoethylene groups and urethane groups {4C}; 25 pbw N-vinyl-N-methylacetoamide {VMA}; 5 pbw cyclohexyl methacrylate {CH}; 1 pbw ethyleneglycol dimethacrylate {ED} and 0.5 pbw 2,4,6-trimethylbenzoyldiphenylphosphinoxide {TPO} (¶ 307). The resulting lens has a water content of 32% and an oxygen permeability {Dk} (¶ 256-257) of 125 (x 10^{-11} cm^2/sec) (¶307).

Iwata *et al.* does not teach 1-methyl-3-methylene-2-pyrrolidone as the pyrrolidone derivative. However, Shibata *et al.* teaches a contact lens composition comprising 1-methyl-3-methylene-2-pyrrolidone [instant claims 1, 4] (1:1-5; 1:54-62, 2:1-14), in conjunction with N-VP, and in an amount of 30 to 70 parts by weight of total hydrophilic monomers (2:46-61). Iwata *et al.* and Shibata *et al.* are analogous art because they are concerned with a similar

technical difficulty, namely the preparation of contact lenses. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined 1-methyl-3-methylene-2-pyrrolidone, as taught by Shibata *et al.* in the invention of Iwata *et al.*, and would have been motivated to do so since Shibata *et al.* suggests that such pyrrolidones provide good polymerizability with (meth)acryloyl groups, thereby decreasing poor optical and mechanical properties resulting from phase separation (1:40-62), as well as no substantial elution of a non-crosslinked N-MMP polymer is observed, and thus, the contact lens is highly safe for the eyes (4:63-5:3).

At the time of invention a person of ordinary skill in the art would have found it obvious to have combined 1-methyl-5-methylene-2-pyrrolidone [instant claim 6], and 5-methyl-3-methylene-2-pyrrolidone [instant claim 8], which are regioisomers of 1-methyl-3-methylene-2-pyrrolidone. A prima facie case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities. "An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties." In re Payne, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979) [see MPEP 2144.09].

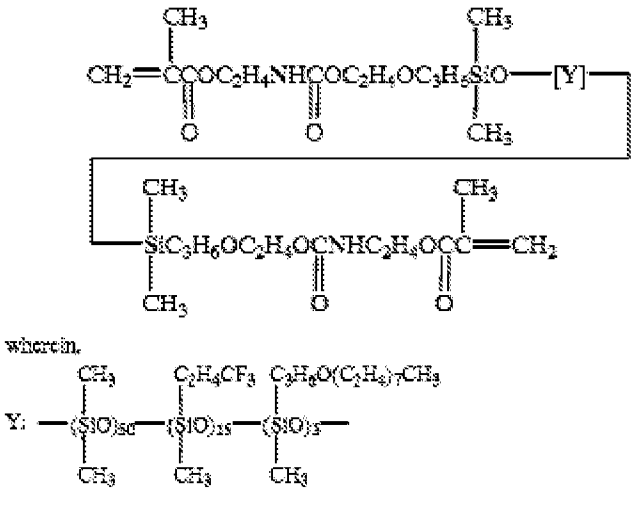
The Office realizes that all the claimed effects or physical properties are not positively stated by the combined references. However, the reference teaches all of the claimed reagents and was prepared under similar conditions. Therefore, the claimed effects and physical properties, i.e. a water content of 32-55% and an oxygen permeability {Dk} of not less than 51 ($\times 10^{-11}$ cm^2/sec), would implicitly be achieved by a composition with all the claimed

ingredients. If it is the applicants' position that this would not be the case: (1) evidence would need to be presented to support applicant's position; and (2) it would be the Office's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects with only the claimed ingredients.

Katagiri *et al.* provides evidence of copolymerization of N-methyl-3-methylene-2-pyrrolidone with silicone (meth)acrylates in contact lens formulations (¶ 1, 18-19, 23-28, 48).

Regarding claim 9: Iwata *et al.* teaches the repeating number of polydimethylsiloxane is 50

(C3)



(¶ 276-277; (C3)).

Regarding claim 10: Iwata *et al.* teaches the basic claimed composition [as set forth above with respect to claim 1].

The Office realizes that all the claimed effects or physical properties are not positively stated by the reference. However, the reference teaches all of the claimed reagents and was prepared under similar conditions. Therefore, the claimed effects and physical properties, i.e. a tensile modulus of 0.2 to 0.8 MPa, and a stress relaxation under loading a fixed load for 30

seconds is 8 to 15%, would implicitly be achieved by a composition with all the claimed ingredients. If it is the applicants' position that this would not be the case: (1) evidence would need to be presented to support applicant's position; and (2) it would be the Office's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects with only the claimed ingredients.

Regarding claims 15-16: Iwata *et al.* and of Shibata *et al.* renders the basic claimed composition obvious [as set forth above with respect to claim 1]; wherein Iwata *et al.* disclose additional monomers such as N,N-dimethylacrylamide (¶ 86, 106, 166, 311; Table 2).

Iwata *et al.* does not specifically disclose ex. 14 or 35 containing N,N-dimethylacrylamide. However, Iwata *et al.* disclose that N,N-dimethylacrylamide can be included in the lens formulation, as N,N-dimethylacrylamide has good compatibility with the hydrophilic polysiloxane monomer (¶ 166). At the time of invention a person of ordinary skill in the art would have found it obvious to have included N,N-dimethylacrylamide in the lens formulation based on the invention of Iwata *et al.*, and would have been motivated to do so since Iwata *et al.* suggests that N,N-dimethylacrylamide can further improve surface wettability of the polymer and modify the water content (¶ 166).

Claims 19-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwata *et al.* (US 2002/0016383) in view of Shibata *et al.* (US 4,547,543), when taken with Katagiri *et al.* (JP 06-214197) {English machine translation of Katagiri *et al.* (JP 06-214197) was used}.

Regarding claims 19, 21, and 25-26: Iwata *et al.* disclose a method for producing a long wearable soft contact lenses (¶ 1-2), wherein a lens formulation {ex. 14} comprising 60 parts by

weight {pbw} of polysiloxane dimethacrylate having polyoxoethylene groups and urethane groups {C3 (¶ 276-277)}; 35 pbw N-vinylpyrrolidone {NVP}; 5 pbw cyclohexyl methacrylate {CH}; 1 pbw ethyleneglycol dimethacrylate {ED} (¶ 170), and 0.5 pbw 2,4,6-trimethylbenzoyldiphenylphosphinoxide {TPO} (¶ 294) was photopolymerized in a mold, dipped in ethyl alcohol overnight, then dipped in water followed by heating at 90 ^{o}C for 3 h (¶ 291, 294). Iwata *et al.* disclose the surface of the lens may be modified by applying plasma treatment (¶ 181). The resulting lens has a water content of 38% and an oxygen permeability {Dk} (¶ 256-257) of 81 (x 10^{-11} cm^2/sec) (¶ 312; Table 3, ex. 14). Iwata *et al.* disclose ex. 35 comprising 50 parts by weight {pbw} of polysiloxane dimethacrylate having polyoxoethylene groups and urethane groups {4C}; 25 pbw N-vinyl-N-methylacetoamide {VMA}; 5 pbw cyclohexyl methacrylate {CH}; 1 pbw ethyleneglycol dimethacrylate {ED} and 0.5 pbw 2,4,6-trimethylbenzoyldiphenylphosphinoxide {TPO} (¶ 307). The resulting lens has a water content of 32% and an oxygen permeability {Dk} (¶ 256-257) of 125 (x 10^{-11} cm^2/sec) (¶307).

Iwata *et al.* does not teach 1-methyl-3-methylene-2-pyrrolidone as the pyrrolidone derivative. However, Shibata *et al.* teaches a contact lens composition comprising 1-methyl-3-methylene-2-pyrrolidone (1:1-5; 1:54-62, 2:1-14), in conjunction with N-VP, and in an amount of 30 to 70 parts by weight of total hydrophilic monomers (2:46-61). Iwata *et al.* and Shibata *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of contact lenses. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined 1-methyl-3-methylene-2-pyrrolidone, as taught by Shibata *et al.* in the invention of Iwata *et al.*, and would have been motivated to do so since Shibata *et al.* suggests that such pyrrolidones provide good polymerizability with (meth)acryloyl

groups, thereby decreasing poor optical and mechanical properties resulting from phase separation (1:40-62), as well as no substantial elution of a non-crosslinked N-MMP polymer is observed, and thus, the contact lens is highly safe for the eyes (4:63-5:3).

The Office realizes that all the claimed effects or physical properties are not positively stated by the combined references. However, the reference teaches all of the claimed reagents and was prepared under similar conditions. Therefore, the claimed effects and physical properties, i.e. a water content of 32-55% and an oxygen permeability {Dk} of not less than 51 (x 10^{-11} cm^2/sec), would implicitly be achieved by a composition with all the claimed ingredients. If it is the applicants' position that this would not be the case: (1) evidence would need to be presented to support applicant's position; and (2) it would be the Office's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects with only the claimed ingredients.

Katagiri *et al.* provides evidence of copolymerization of N-methyl-3-methylene-2-pyrrolidone with silicone (meth)acrylates in contact lens formulations (¶ 1, 18-19, 23-28, 48).

Regarding claim 20: Iwata *et al.* and of Shibata *et al.* renders the basic claimed composition obvious [as set forth above with respect to claim 1]; wherein Iwata *et al.* disclose additional monomers such as N,N-dimethylacrylamide (¶ 86, 106, 166, 311; Table 2).

Iwata *et al.* does not specifically disclose ex. 35 containing N,N-dimethylacrylamide. However, Iwata *et al.* disclose that N,N-dimethylacrylamide can be included in the lens formulation, as N,N-dimethylacrylamide has good compatibility with the hydrophilic polysiloxane monomer (¶ 166). At the time of invention a person of ordinary skill in the art would have found it obvious to have included N,N-dimethylacrylamide in the lens formulation

based on the invention of Iwata *et al.*, and would have been motivated to do so since Iwata *et al.* suggests that N,N-dimethylacrylamide can further improve surface wettability of the polymer and modify the water content (¶ 166).

Regarding claim 22: Iwata *et al.* disclose additives such as dyes, pigments, and/or UV absorbers (¶ 176).

Regarding claim 23-24: Iwata *et al.* disclose solvents such as ethanol, dimethylsulfoxide, and dimethylforamide can be added to adjust the degree of polymerization or the lens swelling ratio (¶ 177).

Iwata *et al.* does not specifically disclose 0.1 to 5 wt% of solvents. However, it has been well established that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) [MPEP 2144.05]. At the time of invention a person of ordinary skill in the art would have found it obvious to have optimized the amount of solvent, as taught by Iwata *et al.*, as commonly practiced in the art, and would have been motivated to do so since the degree of polymerization or lens swelling ratio is influenced by the amount of solvent.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iwata *et al.* (US 2002/0016383) in view of Shibata *et al.* (US 4,547,543), as applied to claim 26 above, and further in view of Valiant, JR. *et al.* (US 2002/0102415).

Regarding claim 27: Iwata *et al.* and Shibata *et al.* renders the basic claimed method obvious [as set forth above with respect to claim 26].

Iwata *et al.* does not teach a plasma treatment with a mixture of oxygen and water [instant claim 27]. However, Valiant, JR. *et al.* teaches a method for surface treating contact lens material comprising a plasma treatment with a mixture of oxygen and water {air drawn through 5% hydrogen peroxide solution} [instant claim 27] (¶ 10, 58). Iwata *et al.* and Valiant, JR. *et al.* are analogous art because they are concerned with a similar technical difficulty, namely plasma treatment of contact lenses. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined plasma treatments in the presence of oxygen and water, as taught by Valiant, JR. *et al.* in the invention of Iwata *et al.*, and would have been motivated to do so since Valiant, JR. *et al.* suggests that such strong oxidizing plasma promote adhesion for bonding of the subsequent carbon deposition layer (¶ 58).

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iwata *et al.* (US 2002/0016383) in view of Shibata *et al.* (US 4,547,543), as applied to claim 26 above, and further in view of Hayashi *et al.* (US 6,503,632).

Regarding claim 28: Iwata *et al.* and Shibata *et al.* renders the basic claimed method obvious [as set forth above with respect to claim 26].

Iwata *et al.* does not teach a plasma treatment with a mixture of oxygen and tetrafluoromethane [instant claim 28]. However, Hayashi *et al.* teaches a method for surface treating contact lens material comprising a plasma treatment with a mixture of oxygen and tetrafluoromethane [instant claim 28] (1:10-18; 21:7-15). Iwata *et al.* and Hayashi *et al.* are analogous art because they are concerned with a similar technical difficulty, namely plasma treatment of contact lenses. At the time of invention a person of ordinary skill in the art would

have found it obvious to have combined plasma treatments in the presence of oxygen and tetrafluoromethane, as taught by Hayashi *et al.* in the invention of Iwata *et al.*, and would have been motivated to do so since Hayashi *et al.* suggests that such plasma treatment provide a substrate with substituents which a chemical reaction can proceed {the surface of the molded article may be chemically bonded further with a polymer or monomer} (21:16-23).

Claims 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwata *et al.* (US 2002/0016383) in view of Shibata *et al*. (US 4,547,543), as applied to claim 26 above, and further in view of Walther *et al.* (US 6,379,004).

Regarding claims 29-30: Iwata *et al.* and Shibata *et al*. renders the basic claimed method obvious [as set forth above with respect to claim 26].

Iwata *et al.* does not teach a plasma treatment with a mixture of oxygen and organic silane [instant claim 29], specifically tetramethoxysilane [instant claim 30]. However, Walther *et al.* teaches a method for surface treating ophthalmic lens material comprising a plasma treatment with a mixture of oxygen and tetramethoxysilane [instant claims 29-30] (1:4-6; 10:48-62). Iwata *et al.* and Walther *et al.* are analogous art because they are concerned with a similar technical difficulty, namely plasma treatment of ophthalmic lenses. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined plasma treatments in the presence of oxygen and tetramethoxysilane, as taught by Walther *et al.* in the invention of Iwata *et al.*, and would have been motivated to do so since Walther *et al.* suggests that such plasma treatment provide a substrate with both an interface layer and a grease protection layer (10:48-50).

Claims 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwata *et al.* (US 2002/0016383) in view of Shibata *et al.* (US 4,547,543), as applied to claim 26 above, and further in view of Turek *et al.* (US 2002/0137811).

Regarding claims 31-35: Iwata *et al.* and Shibata *et al.* renders the basic claimed method obvious [as set forth above with respect to claim 26].

Iwata *et al.* does not teach a plasma treatment with a mixture of oxygen and methane [instant claim 31], and a mixture of oxygen, nitrogen, and methane [instant claim 32]. Iwata *et al.* does not teach a surface treatment that is a coating method of a hydrophilic polymer coating [instant claim 33], specifically plasma polymerization of hydrophilic monomers [instant claim 34], and plasma-induced graft polymerizations [instant claim 35]. However, Turek *et al.* teaches a method for surface treating ophthalmic lens material comprising a plasma treatment with a mixture of oxygen and methane [instant claim 31], and a mixture of air {oxygen and nitrogen} and methane [instant claim 32] (¶105-110). Turek *et al.* also teaches a method for surface treating ophthalmic lens material comprising a plasma treatment coating method of a hydrophilic polymer coating [instant claim 33], specifically plasma polymerization of hydrophilic monomers [instant claim 34], and plasma-induced graft polymerizations [instant claim 35] (¶105-110). Iwata *et al.* and Turek *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the surface treating of ophthalmic lenses. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined plasma treatments in the presence of air and methane, and plasma induced polymerizations, as taught by Turek *et al.* in

the invention of Iwata *et al.*, and would have been motivated to do so since Turek *et al.* suggests that such plasma treatments provide a surface which is more ophthalmically compatible (¶ 106).

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iwata *et al.* (US 2002/0016383) in view of Shibata *et al.* (US 4,547,543), as applied to claim 19 above, and further in view of Niwa *et al.* (US 5,516,467).

Regarding claim 36: Iwata *et al.* and Shibata *et al.* renders the basic claimed method obvious [as set forth above with respect to claim 19].

Iwata *et al.* does not teach a method of coloring the ocular lens material by using a vat dye [instant claim 36]. However, Niwa *et al.* teaches a method for coloring contact lenses by using a vat dye [instant claim 36] (1:4-8; 2:26-49). Iwata *et al.* and Niwa *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the coloring of contact lenses. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined vat dyes, as taught by Niwa *et al.* in the invention of Iwata *et al.*, and would have been motivated to do so since Niwa *et al.* suggests that such vat dyes can be uniformly dispersed in the monomer mixture (2:64-3:10; 3:30-40).

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iwata *et al.* (US 2002/0016383) in view of Shibata *et al.* (US 4,547,543), when taken with Katagiri *et al.* (JP 06-214197) {English machine translation of Katagiri *et al.* (JP 06-214197) was used}.

Regarding claim 37: Iwata *et al.* disclose a method for producing a long wearable soft contact lenses (¶ 1-2), wherein a lens formulation {ex. 14} comprising 60 parts by weight {pbw}

of polysiloxane dimethacrylate having polyoxoethylene groups and urethane groups {C3 (¶ 276-277)}; 35 pbw N-vinylpyrrolidone {NVP}; 5 pbw cyclohexyl methacrylate {CH}; 1 pbw ethyleneglycol dimethacrylate {ED} (¶ 170), and 0.5 pbw 2,4,6-trimethylbenzoyldiphenylphosphinoxide {TPO} (¶ 294) was photopolymerized in a mold, dipped in ethyl alcohol overnight, then dipped in water followed by heating at 90 ^{o}C for 3 h (¶ 291, 294). Iwata *et al.* disclose the surface of the lens may be modified by applying plasma treatment (¶ 181). The resulting lens has a water content of 38% and an oxygen permeability {Dk} (¶ 256-257) of 81 (x 10^{-11} cm^2/sec) (¶ 312; Table 3, ex. 14). Iwata *et al.* disclose ex. 35 comprising 50 parts by weight {pbw} of polysiloxane dimethacrylate having polyoxoethylene groups and urethane groups {4C}; 25 pbw N-vinyl-N-methylacetoamide {VMA}; 5 pbw cyclohexyl methacrylate {CH}; 1 pbw ethyleneglycol dimethacrylate {ED} and 0.5 pbw 2,4,6-trimethylbenzoyldiphenylphosphinoxide {TPO} (¶ 307). The resulting lens has a water content of 32% and an oxygen permeability {Dk} (¶ 256-257) of 125 (x 10^{-11} cm^2/sec) (¶307).

Iwata *et al.* does not teach 1-methyl-3-methylene-2-pyrrolidone as the pyrrolidone derivative. However, Shibata *et al.* teaches a contact lens composition comprising 1-methyl-3-methylene-2-pyrrolidone (1:1-5; 1:54-62, 2:1-14), in conjunction with N-VP, and in an amount of 30 to 70 parts by weight of total hydrophilic monomers (2:46-61). Iwata *et al.* and Shibata *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of contact lenses. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined 1-methyl-3-methylene-2-pyrrolidone, as taught by Shibata *et al.* in the invention of Iwata *et al.*, and would have been motivated to do so since Shibata *et al.* suggests that such pyrrolidones provide good polymerizability with (meth)acryloyl

groups, thereby decreasing poor optical and mechanical properties resulting from phase separation (1:40-62), as well as no substantial elution of a non-crosslinked N-MMP polymer is observed, and thus, the contact lens is highly safe for the eyes (4:63-5:3).

The Office realizes that all the claimed effects or physical properties are not positively stated by the combined references. However, the reference teaches all of the claimed reagents and was prepared under similar conditions. Therefore, the claimed effects and physical properties, i.e. a water content of 32-55% and an oxygen permeability {Dk} of not less than 51 (x 10^{-11} cm^2/sec), would implicitly be achieved by a composition with all the claimed ingredients. If it is the applicants' position that this would not be the case: (1) evidence would need to be presented to support applicant's position; and (2) it would be the Office's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects with only the claimed ingredients.

Katagiri *et al.* provides evidence of copolymerization of N-methyl-3-methylene-2-pyrrolidone with silicone (meth)acrylates in contact lens formulations (¶ 1, 18-19, 23-28, 48).

Response to Arguments

Applicant's arguments with respect to claims 1-37 have been considered but are moot in view of the new ground(s) of rejection.

Shibata *et al.* (US 4,547,543) was relied on for disclosing a contact lens composition comprising 1-methyl-3-methylene-2-pyrrolidone (1:1-5; 1:54-62, 2:1-14), in conjunction with N-VP, and in an amount of 30 to 70 parts by weight of total hydrophilic monomers (2:46-61).

Katagiri *et al.* (JP 06-214197) was relied on to provide evidence of copolymerization of N-methyl-3-methylene-2-pyrrolidone with silicone (meth)acrylates in contact lens formulations

(¶ 1, 18-19, 23-28, 48) {the prior art discloses polymerization of silicone (meth)acrylates with N-methyl-3-methylene-2-pyrrolidone; it is known to copolymerize silicone (meth)acrylates and N-methyl-3-methylene-2-pyrrolidone for the formation of soft contact lenses}.

Valiant, JR. *et al.* (US 2002/0102415) was relied on for disclosing a method for surface treating contact lens material comprising a plasma treatment with a mixture of oxygen and water {air drawn through 5% hydrogen peroxide solution} (¶ 10, 58).

Hayashi *et al.* (US 6,503,632) was relied on for disclosing a method for surface treating contact lens material comprising a plasma treatment with a mixture of oxygen and tetrafluoromethane (1:10-18; 21:7-15).

Walther *et al.* (US 6,379,004) was relied on for disclosing method for surface treating ophthalmic lens material comprising a plasma treatment with a mixture of oxygen and tetramethoxysilane (1:4-6; 10:48-62).

Turek *et al.* (US 2002/0137811) was relied on for disclosing a method for surface treating ophthalmic lens material comprising a plasma treatment with a mixture of oxygen and methane, and a mixture of air {oxygen and nitrogen} and methane (¶105-110).

Niwa *et al.* (US 5,516,467) was relied on for disclosing a method for coloring contact lenses by using a vat dye (1:4-8; 2:26-49).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pepitone whose telephone number is 571-270-3299. The examiner can normally be reached on M-F, 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MFP
25-August-10

/Mark Eashoo/

Supervisory Patent Examiner, Art Unit 1796